UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,797	04/21/2004	Herbert M. Dean	dean0404con	5067

23580 7590 06/03/2008

MESMER & DELEAULT, PLLC
41 BROOK STREET
MANCHESTER, NH 03104

EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
06/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,797	DEAN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2008 has been entered.

Claims 15-20 are pending in this application.

Applicants' arguments filed March 5, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 17, 19 and 20 are drawn to a method for secondary cardiovascular prevention in a "non-hypertensive patent". There is no mention of the exclusion of hypertensive patients found in the instant specification. This is a new matter rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Krumholz et al. Annals of Internal Medicine 1996 Vol. 124 No. 3.

Krumholz teach that patients treated with aspirin (a platelet inhibitor) during hospitalization and patients prescribed beta blockers as a discharge medication were much more likely to be treated with aspirin at discharge (page 297, column 2) for secondary prevention after acute myocardial infarction. Further, in this study, the prescribed use of aspirin at discharge was correlated with several indicators of better overall health status. The prescribed use of aspirin at discharge was also associated

with several specific patterns of care, including, *inter alia*, beta-blocker therapy at discharge (page 292 column 1 "Results"). Since no details are given regarding the "single dosage unit" the language of the claim reads on two single agents, an aspirin tablet and a beta blocker tablet, in a container to be administered together, such as a dosage cup, routinely employed to administer medication to hospitalized patients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krumholz et al as applied to claim 15 above, and further in view of Byrne et al. U.S. Patent No. 5,156,849.

Krumholz teach that patients treated with aspirin (a platelet inhibitor) during hospitalization and patients prescribed beta blockers as a discharge medication were much more likely to be treated with aspirin at discharge (page 297, column 2) for secondary prevention after acute myocardial infarction. Further, in this study, the prescribed use of aspirin at discharge was correlated with several indicators of better overall health status. The prescribed use of aspirin at discharge was also associated with several specific patterns of care, including, *inter alia*, beta-blocker therapy at discharge (page 292 column 1 "Results"). Regarding the combination of aspirin and a beta-blocker in a single dosage unit, Byrne et al. teach the combination of aspirin and beta-blockers in a single dosage unit.

Claims 17, 19 and 20 contain the proviso that the patient is not hypertensive. The Krumholz et al. reference does not disclose the treatment of a hypertensive patient and as such anticipates claims to treatment of non-hypertensive patients.

It would have been made obvious to one of ordinary skill in art at the time it was made to employ a beta-adrenergic blocking agent with a platelet inhibitor to prevent secondary heart attacks motivated by the teaching of Krumholz et al. who disclose that

the prescribed use of aspirin at discharge was correlated with several indicators of better overall health status and was also associated with beta blocker therapy at discharge (page 292 column 1 "Results"). To encompass both agents in a single dosage unit would have been obvious motivated by the teaching of Byrne et al. who discloses a specific formulation for the combination of aspirin and beta adrenergic blocking agents in a single dosage unit.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Regarding the priority to 60/222,249, Applicant states that the last paragraph of page 1 and the first paragraph of page 2 of the provisional application and paragraph [0003] of the present application there are disclosed "primary prevention" trials and secondary prevention trials. The Examiner notes that in these sections of the disclosure, the subset of patients only includes those with occlusive vascular disease. Applicant has broadened the scope to include any patient in whom secondary cardiovascular prevention is desired (claims 15 and 16) and patients that are not hypertensive in whom secondary cardiovascular prevention is desired (claims 17-20). Regarding the subset of patients that are non-hypertensive, there doesn't seem to be any disclosure relating to that specific subset of patients. Applicant further states that

"utilizing after a heart attack" and "secondary prevention of heart attacks" are understood by those of ordinary skill in the art as being synonymous and states that there is sufficient basis and recitation in both the provisional and the present application that supports secondary prevention, for example, use after a heart attack. In response, the American Heart Association defines secondary prevention as "Identifying and treating people with established disease and those at very high risk of developing cardiovascular disease" and "treating and rehabilitating patients who've had a heart attack or stroke to prevent another cardiovascular or cerebrovascular event". There is no recitation of a patient that necessarily has hypertension, or lack thereof. Applicant's reliance on Krumholz et al. to expand the instant specification is not well taken. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in his opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05. In particular, while Applicant's specification as originally filed contained a generic disclosure of "primary prevention" trials and "secondary trials" drawn to subsets of patient population with a history of "occlusive vascular disease" and a recitation of lives saved by use of aspirin to "reduce subsequent incidence of heart attack, stroke and death", such does not entitle Applicants to now claim a method for secondary cardiovascular prevention in a non-hypertensive patient because such represents a

subgenus that were not previously set forth or that would have been immediately envisaged by one skilled in the art from the specification as originally filed.

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept of "secondary cardiovascular prevention in a non-hypertensive patient". Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in In re Swinehart, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought. **Any negative limitation or exclusionary proviso must have basis in the original disclosure**. The mere absence of a positive recitation is not basis for exclusion.

Regarding Krumholz et al., Applicant relies on the specification teachings of paragraph [0009] that states the desire to incorporate the desired β adrenergic blocking agent and platelet inhibitors into a "single dosage unit". and paragraph [0020] and [0028] that describes the agents being incorporated into a single formulation. It is well established that the specification teaches an invention, whereas the claims define the **right to exclude**. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 [227

USPQ 577] n.14 (Fed. Cir. 1985). Further, Applicant has provided no guidance as to how one would put these two agents together in a single formulation and has not provided any data relating to compatibility of these two agents in a single formulation. The convenience of putting the desired β adrenergic blocking agent and platelet inhibitors into a "single dosage unit, though perhaps a matter of great convenience, did not produce a "new" or "different" function and to those skilled in the art, the use of the old elements in combination is clearly anticipated by the prior art.

Applicant asserts that Byrne contains no teaching or suggestion for secondary prevention of a heart attack and Krumholz also contains no teaching of β blockers for secondary prevention of heart attacks. In response, Krumholz teaches administration of aspirin and β blockers to patients being discharged from the hospital after a heart attack. This, by definition of the American Heart Association is secondary prevention (The American Heart Association defines secondary prevention as "Identifying and treating people with established disease and those at very high risk of developing cardiovascular disease" and "treating and rehabilitating patients who've had a heart attack or stroke to prevent another cardiovascular or cerebrovascular event").

Applicant states that Krumholz et al. finds that 24% of patients that might have benefited from aspirin at hospital discharge did not receive this treatment, despite that it is acknowledged to prevent future heart attacks and 66% of patients who might have benefited from β blockers at hospital discharge did not receive this treatment. In response, the reference is clearly drawn to the beneficial effects of treatment with aspirin and β blockers upon discharge for prevention of secondary heart attack.

However, if applicant is stating that the data in the Krumholz et al. reference teaches away, a reference is no less obvious if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference "teaches away" from the invention is inapplicable to an obviousness analysis." Bristol-Myers Squibb Co., 246 F.3d at 1378 (quoting Celeritas Techs., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 [47 USPQ2d 1516] (Fed. Cir. 1998)).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

May 28, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614